17 January 2020
EMA/28170/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 21-23 January 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

21 January 2020, 09:00 – 23 January 2020, 13:00 - Room 2C

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of competing interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP Secretariat at the start of meeting.

Disclaimers

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the agenda

ii. Intended participation and competing interests

iii. Declaration of contacts between members and companies with regard to points on the agenda

iv. Adoption of the minutes of the previous meeting

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 2C)	Tue 21 January 2020	16:30-20:00 (TBC)

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/005009/FULL/0001 *Porcine*	**ORAL EXPLANATION – Tuesday 21 January 2020, time 14:30** ***For discussion:*** Rapporteurs' assessment of responses to list of outstanding issues; rapporteur's EPMAR

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/005302/FULL/0001 *Horses*	***For decision:*** Clock stop extension request

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/005057/0000 *New vaccine* *Chickens*	***For decision:*** Need for an oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005058/0000 *New vaccine* *Chickens*	***For decision:*** Need for an oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005199/0000 *New product* *Cattle, pigs, sheep*	***For decision:*** Need for an oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/005184/0000 *New vaccine* *Pigs*	***For adoption:*** CVMP scientific overview and list of questions, comments on the product information
• **Product** EMEA/V/C/005301/0000 *New vaccine* *Rabbits*	***For adoption:*** CVMP scientific overview and list of questions, comments on the product information
• **Product** EMEA/V/C/005180/0000 *New product* *Dogs*	***For adoption:*** Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Stelfonta** (EMEA/V/C/005018/0000)
- ***For endorsement:*** EPAR scientific discussion for **Aservo EquiHaler** (EMEA/V/C/004991/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Innovax-ND-IBD** EMEA/V/C/004422/II/0003 *To add a new indication*	Rapp: J. Poot ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Rabitec** EMEA/V/C/004387/II/0002 *To extend the duration of immunity*	Rapp: E. Werner Co-rapp: K. Kivilahti-Mantyla ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary opinion
• **Bravecto** EMEA/V/C/002526/II/0039 *Quality-related changes*	Rapp: G. J. Schefferlie ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Clevor** EMEA/V/C/004417/II/0005/G *Quality-related changes*	Rapp: C. Muñoz ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

Information on certain topics discussed under section 3.2 cannot be released at the present time as it is deemed to be confidential

3.3 List of questions

• **UpCard** EMEA/V/C/003836/II/0005/G *Quality-related changes*	Rapp: C. Muñoz ***For adoption***: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Afoxolaner Merial** EMEA/V/C/005126/II/0003 *To change the legal status*	Rapp: P. Hekman Co-rapp: J. G. Beechinor ***For information***: Letter of withdrawal of the variation application

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- No items

4.2 Article 34 of Directive 2001/82/EC

• **Adjusol tmp sulfa liquide and its associated names** EMEA/V/A/134 *Harmonisation of SPC*	Rapp: C. Muñoz Co-rapp: S. Louet ***For decision:*** Request from Virbac for an extension of the clock-stop ***For adoption:*** Revised timetable

4.3 Article 35 of Directive 2001/82/EC

• **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** EMEA/V/A/136 *Withdrawal periods*	Rapp: S. Louet Co-rapp: G. J. Schefferlie ***For decision:*** Need for list of outstanding issues ***For discussion:*** Rapporteur's assessment report; co-rapporteur's assessment report

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

- No items

4.7 Other issues

- No items

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

Information on certain topics discussed under section 5.2 cannot be released at the present time as it is deemed to be confidential

5.3 Product anniversary list

Product	**Period**
Acticam (EMEA/V/C/000138)	09/12/2018 – 08/12/2019
Activyl Tick Plus (EMEA/V/C/002234))	09/01/2019 – 08/01/2020
Bovela (EMEA/V/C/003703)	22/12/2018 – 21/12/2019
BTVPUR (EMEA/V/C/002231)	17/12/2018 – 16/12/2019
Cepedex (EMEA/V/C/004376)	13/12/2018 – 12/12/2019
Coliprotec F4/F18 (EMEA/V/C/004225)	09/01/2019 – 08/01/2020
Contacera (EMEA/V/C/002612)	06/12/2018 – 05/12/2019
Cortavance (EMEA/V/C/000110)	09/01/2019 – 08/01/2020
Galliprant (EMEA/V/C/004222)	09/01/2019 – 08/01/2020
Halagon (EMEA/V/C/004201)	13/12/2018 – 12/12/2019
Imrestor (EMEA/V/C/002763)	09/12/2018 – 08/12/2019
Inflacam (EMEA/V/C/002497)	09/12/2018 – 08/12/2019
Isemid (EMEA/V/C/004345)	09/01/2019 – 08/01/2020
Meloxidyl (EMEA/V/C/000115)	15/01/2019 – 14/01/2020
Metacam (EMEA/V/C/000033)	07/01/2019 – 06/01/2020
NexGard Spectra (EMEA/V/C/003842)	15/01/2019 – 14/01/2020
Onsior (EMEA/V/C/000127)	16/12/2018 – 15/12/2019
Panacur AquaSol (EMEA/V/C/002008)	09/12/2018 – 08/12/2019

Product	Period
Porcilis PCV (EMEA/V/C/000135)	12/01/2019 – 11/01/2020
Prac-tic (EMEA/V/C/000103)	18/12/2018 – 17/12/2019
Respiporc FLU3 (EMEA/V/C/000153)	14/01/2019 – 13/01/2020
Rheumocam (EMEA/V/C/000121)	10/01/2019 – 09/01/2020
SevoFlo (EMEA/V/C/000072)	11/12/2018 – 10/12/2019
Syvazul BTV (EMEA/V/C/004611)	09/01/2019 – 08/01/2020
Velactis (EMEA/V/C/003739)	09/12/2018 – 08/12/2019
Ypozane (EMEA/V/C/000112)	11/01/2019 – 10/01/2020
Zulvac 8 Bovis (EMEA/V/C/000145)	15/01/2019 – 14/01/2020
Zulvac 8 Ovis (EMEA/V/C/000147)	15/01/2019 – 14/01/2020

5.4 Renewals

• **Sileo** EMEA/V/C/003764/R/0014	Rapp: F. Hasslung Wikström Co-rapp: J. G. Beechinor ***For adoption***: List of outstanding issues
• **Innovax ILT** EMEA/V/C/003869/R/0005	Rapp: E. Werner Co-rapp: L. Nejpechalová ***For adoption:*** List of outstanding issues
• **Canigel L4** EMEA/V/C/004079/R/0007	Rapp: B. Urbain Co-rapp: R. Breathnach ***For adoption***: List of questions

5.5 Pharmacovigilance - PSURs and SARs

• **Credelio** EMEA/V/C/004247	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.2019-31.07.2019
• **Metacam** and **Novem** EMEA/V/C/000033 EMEA/V/C/000086	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.2016-30.04.2019
• **Advocate** EMEA/V/C/000076	Rapp: T.-M. Muhonen ***For discussion***: CVMP assessment report on the PSUR for the period 01.05.2016-30.04.2019

• **Activyl** EMEA/V/C/000163	Rapp: G. J. Schefferlie ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.09.2016-31.08.2019
• **Clomicalm** EMEA/V/C/000039	Rapp: G. Hahn ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2016-31.07.2019
• **Evant** EMEA/V/C/004902	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 05.02.2019-31.08.2019
• **Loxicom** EMEA/V/C/000141	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 11.08.2016-10.08.2019
• **Neocolipor** EMEA/V/C/000035	Rapp: J.-C. Rouby ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.09.2016-31.08.2019
• **Oxybee** EMEA/V/C/004296	Rapp: J. Poot ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.03.2019-31.08.2019
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.03.2019-31.08.2019
• **Startvac** EMEA/V/C/000130	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.09.2016-31.08.2019
• **Suvaxyn Circo** EMEA/V/C/004242	Rapp: F. Klein ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.03.2019-31.08.2019
• **Syvazul BTV** EMEA/V/C/004611	Rapp: C. Muñoz ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 09.01.2019-31.07.2019
• **Vepured** EMEA/V/C/004364	Rapp: N. C. Kyvsgaard ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.03.2019-31.08.2019
• **Versican Plus DHPPI L4** EMEA/V/C/003678	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.06.2018-31.05.2019

• **Zulvac SBV** EMEA/V/C/002781	Rapp: G. Kulcsár ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.09.2018-31.08.2019

5.6 Supervision and sanctions

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

Information on certain topics discussed under section 6.2 cannot be released at the present time as it is deemed to be confidential

6.2 Codex Alimentarius

- ***For information***: Report on the Codex Alimentarius Task Force on Antimicrobial Resistance, 7th session, held on 9-13 December 2019 in PyeongChang, South Korea

6.3 Other EU bodies and international organisations

- ***For decision***: OIE Antimicrobial Working Group (OIE AMR WG): call to appoint supporting expert on poultry diseases - *see also point 8.3*
- ***For discussion and decision***: Summary and conclusions of the 88th meeting of the Joint FAO/WHO Expert Committee on Food Additives

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information on certain topics discussed under section 7 cannot be released at the present time as it is deemed to be confidential

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

7.11 Other working party and scientific group issues

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential

- ***For adoption:*** List of substances considered as not falling within the scope of Regulation (EC) No. 470/2009

8.2 Environmental risk assessment

Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential

8.3 Antimicrobial resistance

- ***For decision:*** OIE Antimicrobial Working Group (OIE AMR WG): call to appoint supporting expert on poultry diseases – *see also point 6.3*

8.4 Pharmacovigilance

- No items

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to be commercially confidential

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential

- ***For decision:*** Transfer of (co-)rapporteurships responsibilities from M. Turk to B. Kolar
- ***For decision:*** Transfer of (co-)rapporteurships responsibilities from J. Bureš to L. Nejpechalová

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information:*** Verbal report from the CMDv chair on the meetings held on 10-11 October, 7-8 November and 5-6 December 2019; draft minutes of the 5-6 December 2019 meeting; draft agenda of the meeting to be held on 23-24 January 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information***: Follow up update on the EMA 'Regulatory science to 2025' veterinary stakeholders' workshop held on 5-6 December 2019

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert groups concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6 on signal detection and adverse events and pharmacovigilance inspections and pharmacovigilance system master file; on pharmacovigilance communication; on format for the collection of data for antimicrobials used in animals; and on rules for oral administration of veterinary medicinal products; on list of antimicrobials reserved for the treatment of certain infections in humans

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Jan 2020	21-23						28-29		21		
Feb 2020	18-19								18		
Mar 2020	17-19						24-25		17		
Apr 2020	21-23								21		
May 2020	18-20						12-13		18		